

Remarks

Claims 1-13 and 15-18 are now pending. Claim 1 has been amended. Claim 14 has been canceled without prejudice. No new matter has been added. The Applicant expressly reserves the right to further prosecute the same or similar claims in subsequent patent applications claiming the benefit of priority to the instant application. 35 U.S.C. §§ 120, 121.

Interview Summary

Submitted herewith is an Interview Summary, dated June 6, 2008, prepared by the Applicant's former counsel, Dr. Patrick Waller (Reg. No. 41,418), corresponding to his in-person interview with the Examiner conducted at the Office on April 10, 2008.

Claim Rejections - 35 U.S.C. § 102(e)

Claims 1 and 14-18 stand rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 6,287,290 to Perkins et al. ("Perkins"). The Applicant respectfully traverses the rejection.

To anticipate a claim under §102, a reference must teach each and every element of the claim, either expressly or inherently. M.P.E.P. § 2131. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union oil Co. of California*, 8144. F. 2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Applicants submit that the cited art does not meet this standard.

Perkins teaches *optionally* sealing or occluding an air passage leading to the collapsed region of the lung by "delivering a plug..., typically at [sic] partially hydrated collagen hydrogel..." *after* the lung has been collapsed by vacuum aspiration or the application of external force. (See column 9, lines 24-29; column 10, lines 37-58; and Figure 4C)

In contrast, the Applicant's claimed methods relate to reducing lung volume by administering a composition comprising an anti-surfactant to a diseased alveolar region of the lung where administering the composition promotes collapse and sealing of the diseased alveolar

region. Moreover, the composition administered in the Applicant's claimed methods comprises an anti-surfactant, which increases the surface tension of fluids lining the diseased alveolar region resulting in collapse of that region. Further, the composition administered in the Applicant's claimed methods also functions as an adhesive or sealant in the diseased alveolar region. In sum, the composition administered in the claimed methods serves to cause collapse of the tissue lining the diseased alveolar region by acting as an anti-surfactant, as well as serving as an adhesive. In support of this summary, the Applicants point the Examiner to paragraph 31 of the published application:

The balloon catheter 50 mentioned above (and described more fully below) is then guided through bronchoscope 10 to target region 20a of lung 20. When catheter 50 is positioned within bronchoscope 10, balloon 58 is inflated so that material passed through the catheter will be contained in regions of the lung distal to the balloon. The targeted region can be lavaged with saline to reduce the amount of surfactant that is naturally present, and a physiologically compatible composition containing an anti-surfactant (i.e., an agent that increases the surface tension of fluids lining the alveoli) is applied to the targeted region of the lung through the catheter. Preferably, the composition is formulated as a solution or suspension and includes fibrin or fibrinogen. An advantage of administering these substances is that they can each act not only as anti-surfactants, but can participate in the adhesive process as well. *Specification at ¶ 0031.*

Critically, Perkins does not teach or suggest promoting stable volume reduction of a targeted region of a patient's lung by administering an anti-surfactant into a diseased alveolar region of a patient's lung to promote collapse. Rather, Perkins discloses the use of a plug to *occlude* the air passage leading to the collapsed tissue region, wherein the collapsed tissue region has previously been collapsed by the application of an external force or vacuum aspiration of the air contained in that region of the lung.

Therefore, Applicant respectfully requests the withdrawal of the rejections under 35 U.S.C. § 102(e).

Claim Rejections - 35 U.S.C. § 103(a)

Perkins in view of Edwardson

Claim 13 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Perkins in view of US Patent No. 5,739,288 to Edwardson et al. (“Edwardson”). The Applicant respectfully traverses the rejection.

To establish a *prima facie* case of obviousness, a number of criteria must be met. For example, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. Moreover, one of ordinary skill in the relevant art must have a reasonable expectation of success in light of the cited reference or combination of references. Importantly, the reasonable expectation of success must be found in the prior art, and may not be based on the Applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); see MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

As discussed above, Perkins teaches delivering a plug to occlude an air passage leading to a region of the lung *after* the lung has been independently collapsed by vacuum aspiration or the application of an external force. Therefore, Perkins does not teach or suggest all of the limitations of the amended claims. Critically, Edwardson does not cure the deficiencies of Perkins vis-à-vis the amended claims. The Examiner asserts that “it would have been obvious to use the fibrin sealant of Edwardson et al. in order to provide an enhanced fibrin formulation for tissue closure thereby improving recovery time.” Even if that were correct, which the Applicant does not concede, using the sealant disclosed by Edwardson in the methods taught by Perkins (i.e., as a plug to occlude an air passage leading to the lung *after* collapse) does not meet all of the limitations of the rejected claims, nor would it lead one of ordinary skill in the art to conceptualize the claimed methods among those alternatives that would be “obvious to try.”

Furthermore, as discussed in MPEP § 2143.02 (VI), the proposed combination of references cannot change the principle of operation of a reference. “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teaching of the references are not sufficient to render the claims *prima facie* obvious.” *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The Applicants respectfully contend that in order to arrive at the methods of the rejected claims based on the

combination of Perkins and Edwardson one of ordinary skill in the art would have to change the principle of operation of Perkins or Edwardson or both.

Based on the foregoing, Applicant respectfully requests withdrawal of the rejection of claim 13 under 35 U.S.C. § 103(a).

Perkins in view of Edwardson and Antanavich

Claims 2-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Perkins in view of Edwardson, and further in view of US Patent No. 5,814,022 to Antanavich et al. (“Antanavich”). Applicant respectfully traverses the rejection.

As discussed above, to establish a *prima facie* case of obviousness, a number of criteria must be met. For example, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. Moreover, one of ordinary skill in the relevant art must have a reasonable expectation of success in light of the cited reference or combination of references. Importantly, the reasonable expectation of success must be found in the prior art, and may not be based on the Applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); see MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Antanavich discloses the design of an apparatus for accurately dispensing tissue sealants, one of which sealants may be “an adhesive protein solution having a fibrinogen content of from 3 to 12%.” Nevertheless, Antanavich does not cure the deficiencies of Perkins and Edwardson vis-à-vis the amended claims because the only relevant contribution from Antanavich to the Examiner’s obviousness rejection is the disclosure of the aforementioned adhesive protein solution. Notwithstanding the fact that rejected claim 2 requires an “anti-surfactant composition compris[ing] 3-12% fibrinogen,” the combination of Perkins and Edwardson, which is discussed in detail above, teaches only delivering a plug (made of Edwardson’s fibrin sealant) to occlude an air passage leading to a region of the lung *after* the lung has been independently collapsed by vacuum aspiration or the application of an external force. Therefore, the combination of Perkins, Edwardson, and Antanavich does not teach all the elements of the amended claims.

Based on the foregoing, the Applicants respectfully request the withdrawal of the rejection of claims 2-12 under 35 U.S.C. § 103(a).

Obviousness-Type Double Patenting

Claims 1-3, 13 and 15 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 15, 22, 23, 31, 55 and 60 of copending Application No. 10/069,307 ("the '307 application").

To expedite prosecution to allowance of the pending claims, the Applicants submit herewith a Terminal Disclaimer corresponding to the '307 application, which complies with the requirements of 37 CFR 1.321(c). The Disclaimer is accompanied by the required fee. 37 CFR 1.321(c).

Fees

The Applicants believe they have provided for all required fees in connection with the filing of this Response. Nevertheless, the Commissioner is hereby authorized to charge any additional required fees due in connection with the filing of this Response to our Deposit Account, **06-1448** reference **ATX-011.04**.

Conclusion

In view of the above amendments and remarks, it is believed that the pending claims are in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is urged to contact the undersigned at (617) 832-1000.

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Date: July 1, 2008

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